

4849. Misbranding of Dr. Williams' Pink Pills. U. S. v. 11 Gross Packages of Dr. Williams' Pink Pills. Tried to the court and a jury. Verdict in favor of the United States. Decree of condemnation, forfeiture, and destruction. Decision of the United States Circuit Court of Appeals for the Third Circuit affirming the decree of the lower court ordering the destruction of the product. (F. & D. No. 6384. I. S. No. 490-k. S. No. E-233.)

On March 19, 1915, the United States attorney for the Eastern District of Pennsylvania, acting upon a report by the Secretary of Agriculture, filed in the District Court of the United States for said district a libel, and, on April 17, 1915, a petition and agreement to amend the libel, praying the seizure and condemnation of 11 gross packages, more or less, of Dr. Williams' Pink Pills, remaining unsold in the original unbroken packages at Philadelphia, Pa., alleging that the article had been shipped and transported from the State of New York into the State of Pennsylvania, and charging misbranding in violation of the Food and Drugs Act, as amended. The article was labeled: (on bottle wrapper), "Dr. Williams Pink Pills for Pale People, trade-mark registered, safe and effective tonic for the blood and nerves for anaemia, diseases due to impoverished blood, such as rheumatism, diseases of women, nervous disorders resulting from malnutrition, including neuralgia, sciatica, St. Vitus' Dance, Useful in locomotor ataxia and partial paralysis. A digestive tonic for dyspepsia and chronic constipation." The circulars accompanying the article contained, among other things, the following: "This remedy is offered the public with full confidence in its efficacy in the treatment of diseases arising from or dependent upon impoverished Blood, such as Anaemia, Chlorosis or Green Sickness, Rheumatism, Lumbago, General Debility, Female Weakness, Leucorrhoea, Tardy, Irregular or Painful Periods, Disturbances due to Change of Life, etc." "As the health of the nerves depends directly upon the condition of the blood these pills are a valuable remedy for Nervous Debility, Nervous Prostration, Sleeplessness, Neuralgia, Sciatica, Sick Headache, and have accomplished beneficial results in the more severe nervous disorders such as St. Vitus' Dance, Partial Paralysis and Locomotor Ataxia." "Locomotor Ataxia.—This is one of the most stubborn of nervous diseases in yielding to treatment of any kind. Cases diagnosed as Locomotor Ataxia and a Partial Paralysis, and having characteristic symptoms have shown beneficial results under this tonic treatment and in the cases under observation the resulting improvement has been lasting." "For Men.—Dr. Williams Pink Pills are valuable for building up the system shattered by excesses or disease, and for the various ills caused thereby, viz: Spermatorrhoea, Impotence, Nervous Despondency, Confusion of Ideas, Irritability of Temper and Pain in the Back and Perinaeum." "For Children.—Parents will find Dr. Williams Pink Pills a safe and effective strengthening medicine for weak and bloodless children. The remedy is also suitable as a nerve tonic for the young and for the treatment of St. Vitus' Dance."

Misbranding of the article was alleged in the libel and amended libel for the reason that the following statements regarding the curative or therapeutic effect of such article appearing on the label of the retail packages aforesaid, to wit, (On wrapper around bottle) "For Anaemia, Diseases due to Impoverished Blood, such as Rheumatism, Diseases of Women; Nervous Disorders resulting from Malnutrition, including Neuralgia, Sciatica, St. Vitus' Dance. Useful in Locomotor Ataxia and Partial Paralysis. A digestive tonic for Dyspepsia and Chronic Constipation." (On circular) "This remedy is offered the public with full confidence in its efficacy in the treatment of diseases arising from or dependent upon impoverished Blood, such as Anaemia, Chlorosis or Green Sickness, Rheumatism, Lumbago, General Debility, Female

Weakness, Leucorrhoea, Tardy, Irregular or Painful Periods, Disturbances due to Change of Life, Etc." "As the health of the nerves depends directly upon the condition of the blood these pills are a valuable remedy for Nervous Debility, Nervous Prostration, Sleeplessness, Neuralgia, Sciatica, Sick Headache, and have accomplished beneficial results in the more severe nervous disorders such as St. Vitus' Dance, Partial Paralysis and Locomotor Ataxia." "Locomotor Ataxia.—This is one of the most stubborn of nervous diseases in yielding to treatment of any kind. Cases diagnosed as Locomotor Ataxia and as Partial Paralysis, and having characteristic symptoms have shown beneficial results under this tonic treatment, and in the cases under observation the resulting improvement has been lasting." "For Men.—Dr. Williams Pink Pills are valuable for building up the system shattered by excesses, or disease, and for the various ills caused thereby, viz: Spermatorrhoea, Impotence, Nervous Despondency, Confusion of Ideas, Irritability of Temper and Pain in the Back and Perinaeum." "For Children.—Parents will find Dr. Williams Pink Pills a safe and effective strengthening medicine for weak and bloodless children. The remedy is also suitable as a nerve tonic for the young and for the treatment of St. Vitus' Dance," were false and fraudulent in that they indicated to the purchaser thereof, and created in the minds of the purchasers thereof the impression and belief, that said article was a remedy for, when in fact it was not a remedy for, anemia, chlorosis or green sickness, rheumatism, lumbago, general debility, female weakness, leucorrhoea, tardy, irregular, or painful periods, nervous debility, nervous prostration, sleeplessness, neuralgia, sciatica, sick headache, St. Vitus' dance, partial paralysis, locomotor ataxia, spermatorrhoea, and impotence, and which said statements were made with the knowledge of their falsity and in reckless and wanton disregard of their truth or falsity, for the purpose of defrauding purchasers.

On April 30, 1915, the Dr. Williams Medicine Co., claimant, Schenectady, N. Y., filed its answer to the libel as amended, and on October 20, 1915, the case having come on for trial before the court and a jury, after the submission of evidence and argument by counsel, the following charge was delivered to the jury on October 25, 1915, by the court (Thompson, D. J.):

Gentlemen of the jury: The case which has been tried before you is a proceeding under the Pure Food and Drugs Act. The proceedings in this case are not brought against an individual, but are brought against certain packages of pills. The act of Congress under which the proceedings are brought was passed for the purpose of preventing the transportation in interstate commerce—that is, from one State to another, of foods, articles of food, or articles of drug which are adulterated for misbranded. In this case the proceeding is brought for the purpose of confiscating or having condemned these packages of pills upon the allegation of the Government that they are misbranded. So that the proceedings have been commenced by a seizure on the part of the Government, the articles in question being seized by the marshal. The Dr. Williams Pink Pills Co. has intervened as the claimant of these pills; that is to say, it comes into court and claims that the pills belong to it, that they are its property, and it denies the statements in the Government's libel, as it is called, on which the Government bases its right to have these pills seized and destroyed. So that that makes the issue in the case, and throws the burden on the Government of proving the facts which are set out in the libel. The object of this particular paragraph of the act under which these proceedings are brought is to prevent the carrying in interstate commerce from one State to another of drugs which are worthless or injurious, when they are transported with false and fraudulent statements as to their curative effects, the object being to protect credulous and ignorant people, and to protect the public generally from having imposed upon them as medicines, things to be used as medicines, drugs which will not perform the functions which it is claimed they will perform, and to prevent people being injured by the use of harmful drugs. In this case the pills are claimed to be misbranded because the packages contain certain statements as to their therapeutic and curative properties, which the Government claims are

false and fraudulent. You have heard the evidence in the case. As I stated, the burden is on the Government to prove what it alleges in its libel. That requires, in a case of this sort, that the statement shall not only be false, but shall be fraudulent. So that there will be a double inquiry of the jury here—first, to ascertain whether the statements are false, and, second, as to whether they are fraudulent. So that in examining into the case it will be necessary for you to examine the labels on the packages, of which you will have copies, and the statements made in the pamphlet or folder that accompanied the packages, and to take into consideration the language used in those statements and ascertain what the statements are. In examining those statements you will give to the language used its ordinary and common meaning, and you will take into consideration what those statements would mean to an ordinarily intelligent man who purchased the pills. Having applied that test to the language in determining what the language as set out means, you will then determine from the evidence whether those statements are false. If they are not false, if the statements are true, then, of course, you need go no further in the case. In determining whether they are false, you will take into consideration the testimony which has been offered on the part of the Government, and the evidence which has been offered on the part of the claimant. There has been a great deal of expert testimony here, testimony, in the first place, on the part of the chemists who analyzed these packages, these pills, and who have testified before you as to what are the contents or the ingredients of the pills. In addition to that there has been medical testimony, the testimony of expert physicians, who have testified as to their opinion as to the therapeutic or curative value of those ingredients, the ingredients which they were informed by the testimony of the chemists were contained in the pills.

In considering expert testimony there has been a good deal said here about it being merely opinion testimony. That is true. The statements of the physicians are merely statements of their opinions, and those opinions are to be considered by you as evidence from which you may draw inferences of fact. The opinions of the experts have more or less value, as they are based on a greater or less amount of experience and learning and opportunities to know what the opinions of other people are who are skilled in the profession as to the therapeutic value of these pills for the ailments for which they are recommended in the statements on the boxes and in the pamphlets as remedies. So that you will take into consideration the testimony of these experts and draw from that testimony such inferences of fact as in your own judgments that testimony warrants.

The question, then, will be whether the statements on these labels are true or are false. If you determine that the statements are true, considering the interpretation which would be conveyed to the mind of the ordinarily intelligent man, then it would be your duty to render a verdict for the defendant. If, on the other hand, you are satisfied from the evidence, from the preponderance of the evidence, that they are false, then you would proceed further to determine whether or not they are fraudulent.

As I stated, the object of this part of the act is to prevent credulous and ignorant people and the public generally from being deceived in the purchase of proprietary medicines such as these are. So that in determining whether they are fraudulent you will take into consideration the statements made on the labels, and determine whether or not the claimant, when it made these statements, had them put upon the bottles, knew them to be false. If it knew them to be false, then you would have no difficulty in determining that they were fraudulent, because it would be the inevitable conclusion, willfully making a false statement, that it intended to defraud. But you are at liberty to go further than that. In determining a man's intent, we are very often, and in fact nearly always, obliged to take into consideration the facts and circumstances accompanying his act. Every man is presumed to intend the natural and probable consequences of his act. So that it is not necessary, and it is impracticable, to go into a man's inner consciousness and find out whether or not he intended a thing, but the law imputes the intent to do the thing which would naturally follow from the act of the person charged with the intention. So that in this case you will take into consideration, in case you go that far with the case, whether these statements made on the label were made with an intent to defraud, or with such willful and gross negligence to inquire into the effect of these medicines before making the statements, that the intent to defraud would be presumed. In case, after a consideration of all of the evidence, you determine that the statements were false, that they were made with

an intent to deceive the public, and the pills were transported with those statements with that intent, then it would be your duty to return a verdict in favor of the Government.

As I stated, the burden of proof in this case is on the part of the Government. It is necessary for you to be convinced by a preponderance of the evidence that the Government has sustained that burden of proof before you would be justified in returning a verdict in its favor.

If, on the other hand, you are satisfied from the evidence that the Government has not sustained that burden of proof, or you are satisfied that the pills were shipped in interstate commerce, with an honest belief on the part of those responsible for making the statements that they would do just what was stated on the labels they would do, then it would be your duty to return a verdict in favor of the defendant.

When you come to consider the statements made in the labels, you will take the statements into consideration in whole and also separately. In other words, if you find that any statement made on these labels or on the folders in relation to the curative or therapeutic value, effect of the pills, was false and fraudulent, then it would be your duty to return a verdict in favor of the Government; that is to say, if any part of those statements is such that you, under the manner of reasoning that I have explained to you, conclude it is false and fraudulent, that would be sufficient to cause a condemnation of the whole of these packages. It is not necessary that all the statements should be false and fraudulent, but if the Government has sustained its contention in regard to any one of them, then it would be your duty to return a verdict in its favor. So that in considering the statements, you will bear that in mind.

I hardly think it is necessary for me to review the statements which are made and which are set out in the Government's libel as having been made on these packages. You have heard all of the evidence, and you will have the labels with you, and you will consider the language in the effect which in your judgment it would convey to the mind of an ordinarily intelligent man. As I read the labels there is no direct statement that these pills are cures for the various sorts of diseases mentioned. The general effect of the statements is that the pills are valuable as a tonic for the blood and nerves, and that they are valuable for use in cases where the ailment is the result of or is accompanied by anemia. So that in considering that you will take those facts into consideration, and determine whether or not it was the intention of this language, interpreting it as an ordinarily intelligent man would, on the part of the claimants to convey the impression that they were to cure or act as a remedy for the diseases and ailments even where the language does not directly say so. If it was the intention so to frame a statement that it conveyed those impressions, and those statements were false, and they were known to be false, or you can infer the intention to defraud, then it would be your duty to return a verdict in favor of the Government. If you do not find that intention, of course you will return a verdict in favor of the defendant.

The district attorney has asked me to charge you on certain points:

"1. It is unnecessary for the Government to prove that all the statements on the label or circular were false and fraudulent. If you believe from the evidence that any one statement as to the curative or therapeutic properties of these pills was false in fact, and that the claimant knew that it was false, then you may find a verdict for the Government."

That point is affirmed.

"2. If you believe from the evidence that as to any one of the ailments for which these pills are recommended by the label or circular, and about which the Government has complained in its libel, these pills would have no beneficial effect whatever, and the claimant knew this, you may find a verdict for the Government."

I will affirm that point.

"3. If you believe from the evidence that any one of the therapeutic claims as to the effect of these pills upon locomotor ataxia, St. Vitus' dance, sciatica, rheumatism, impotence, spermatorrhoea, or partial paralysis was false and was made by the claimant with a reckless and wanton disregard as to whether it was true or false, you may find a verdict for the Government."

I will affirm that point.

The fourth point is declined.

"5. If you believe from the evidence that any one of the therapeutic statements upon the label or circular, and of which the Government complains in its libel, was partly true, but was so artfully worded as to convey a meaning

as to its therapeutic properties which was wholly false, and that the label and circular were so worded for the purpose of deceiving the public, then that statement would be false and fraudulent, and you may find a verdict for the Government."

I will affirm that point.

I will decline the sixth point.

The claimant has requested me to charge you as follows:

"1. The burden is on the Government in this case to prove by the preponderance of the evidence that the statements complained of were both false and fraudulent."

That point is affirmed.

"2. There is a difference between mistaken opinion and false opinion. You can only find that these statements were false if you find that the Government has shown that, apart from any question of opinion, the so-called remedy is absolutely worthless and hence the label demonstrably false."

That is true, but it depends on how you find the question of fact based on the opinion evidence. If you find it as a fact that the statements were false, and known to be false, then, of course, your verdict would be for the Government. If you find as a fact that they were not false, or that being false there was no intent on the part of the defendant, either actual intent or implied intent to defraud, then your verdict would be for the claimant.

The defendant's third point is denied.

The defendant's fourth point is denied.

The fourth and sixth points presented on behalf of the United States, which were refused by the court without being read, are as follows:

"4. If you believe from the evidence that the defendant knew that any one of these therapeutic statements as charged in the libel was false and misleading, you may infer a fraudulent intent and find a verdict for the Government."

"6. If you believe from the evidence that any statement upon the label or circular as to its therapeutic claim was wholly false and one about which there is absolutely no contrariety of medical opinion, you may infer from these facts a fraudulent intent and find a verdict for the Government."

(Exception noted for the United States to the refusal of the court to affirm the fourth and sixth points presented on behalf of the United States.)

(Exception noted for the United States to the affirmance by the court of the defendant's first and second points, by direction of the court.)

The third and fourth points presented on behalf of the claimant, which were refused by the court without being read, read as follows:

"3. Unless you find that the Government has shown that the statements complained of were not the honest expression of Mr. Conde's honest opinion, you can not find that these statements were fraudulent."

"4. Under all the evidence in the case your verdict must be for the defendant."

(Exception noted for the claimant to the refusal of the court to affirm the third and fourth points presented on behalf of the claimant.)

(Exception noted for the claimant to the affirmance by the court of the Government's first, second, third, and fifth points, by direction of the court.)

(Exception noted for the claimant to the court's answer to the second point present on behalf of the claimant, by direction of the court.)

Mr. JONES. I would like to except to the charge because of the failure to make clear just what the difference is between "mistaken opinion" and "false opinion."

(Exception noted for the claimant, as requested, by direction of the court.)

Mr. JONES. I would like to have the Government correspondence go out with the jury.

Mr. STERRETT. I object to those letters going out with the jury—the Government letters.

The COURT. Were they offered in evidence?

Mr. JONES. They were offered in evidence and read.

The COURT. You may send them out with the jury.

Mr. STERRETT. May I have an exception?

The COURT. Yes.

(Exception noted for the United States, by direction of the court.)

Mr. STERRETT. I do not know what they are; that is the only thing.)

The jury thereupon retired, and after due deliberation returned into court with a verdict in favor of the United States; and on October 28, 1915, the said

claimant company by its counsel filed its motion with reasons for a new trial, which was overruled on December 28, 1915, and thereupon a decree of condemnation and forfeiture was entered, and it was ordered by the court that the product should be destroyed by the United States marshal and that the claimant company should pay the costs of the proceedings.

On January 5, 1916, the claimant company filed its petition for a writ of error and assignments of error to the United States Circuit Court of Appeals for the Third Circuit, which was allowed on the same date, and on April 4, 1916, the case was argued in said court before Circuit Judges Buffington, McPherson, and Woolley.

On May 22, 1916, the case having come on for final disposition, the judgment of the lower court was affirmed, as will more fully appear from the following decision by the said Circuit Court of Appeals (Buffington, *Circuit Judge*):

In the court below, the United States filed a libel to forfeit certain packages of pills. Thereupon the Dr. Williams Medicine Company claimed the packages seized, answered the libel, and the case proceeded to trial. After a verdict for the plaintiff and a decree of forfeiture, the claimant sued out this writ.

The claim of forfeiture is based on an alleged misbranding of the packages of pills in violation of an amendment to the Food and Drugs Act, passed August 23, 1912, which provides:

"That for the purpose of this act an article shall also be deemed to be misbranded: In case of drugs * * *. Third, if its package or label shall bear or contain any statement, design, or device, regarding the curative or therapeutic effect of such article, or any of the ingredients or substances contained therein, which is false and fraudulent."

The errors alleged group themselves into rulings on evidence, answers to points and exceptions to the court's charge. Without entering into a discussion of the many refined questions of words, terms, and medical theories with which the general subject is beclouded, we may say that to our mind the words used in the statute are clear in meaning, and the court below tried the case on that basis. The purpose of the act was, in the branding of drugs, to punish false and fraudulent statements regarding the curative or therapeutic effects of such drug or any of its ingredients. It follows, therefore, the case below resolved itself into two questions: First, were the statements regarding the curative or therapeutic effects of these pills false, and, second, were they fraudulent? Without citing in detail the rulings of the court in admitting the evidence, in answering the points and in charging the jury, we may say the court consistently adhered to admitting proof and directing the attention of the jury in points and charge to the two decisive elements of the branding being false and fraudulent. Limiting our extracts to locomotor ataxia alone, we note the branding complained of made the statement that the pills were—

"Useful in locomotor ataxia and partial paralysis. * * * This remedy is offered to the public with full confidence in its efficacy in the treatment of diseases arising from or dependent upon impoverished blood. * * * rheumatism, leucorrhoea. * * * These pills are a valuable remedy for * * * sciatica * * * and have accomplished beneficial results in * * * partial paralysis and locomotor ataxia * * * cases diagnosed as locomotor ataxia and as partial paralysis, and having characteristic symptoms have shown beneficial results under this tonic treatment and in the cases under observation the resulting improvement has been lasting."

The libel alleged that:

"These statements were false and fraudulent in this; that they indicated to the purchaser thereof and created in the minds of the purchasers thereof the impression and belief that the said article was a remedy for, when in fact it was not a remedy for, locomotor ataxia, partial paralysis, etc., and that

"These statements were false and fraudulent in this, that they indicated to the purchaser thereof and created in the minds of the purchasers thereof the impression and belief that the said article was a remedy for, when in fact it was not a remedy for, partial paralysis, locomotor ataxia, etc., which statements were made with the knowledge of their falsity and in reckless and

wanton disregard of their truth or falsity for the purpose of defrauding the purchasers."

In support of its case, the Government called several witnesses, physicians of proven ability, knowledge, and experience, who testified that the pill would not and why it could not have any beneficial effects in locomotor ataxia and the other diseases named. They also testified to the fact that medical opinion was unanimous in so saying. It was also shown, and all of this without contradiction, that the pill was practically the well-known Blaud pill used generally in medical practice. It is complained, however, that the testimony of these witnesses was not competent, being a mere expression of their personal opinion or views. But an examination of the proofs shows that the case was wholly different from one where witnesses were testifying to their personal views upon a controverted question of opinion. The testimony here was of fact, namely, that there was general, uncontroverted consensus of opinion. For example, referring to the effect of these pills, the proofs were:

"Q. How about locomotor ataxia?

"A. Utterly useless.

"Q. Is there any difference at all in medical opinion on that point?

"A. I should say not, as far as I know medical opinion * * *.

"Q. Is there anything known to medicine that can have a beneficial effect upon all these various troubles in one pill?

"A. No, sir.

"Q. Is there any difference of medical opinion on that point?

"A. None whatever. I think medical opinion would be unanimous on that."

In the absence of countervailing proof in such matters, it was manifestly a question for the jury to determine the fair or fraudulent character of the branding statement. This question the court left to it, saying if they were satisfied, "that the pills were shipped in interstate commerce, with an honest belief on the part of those responsible for making the statement that they would do just what was stated on the label they would do, that then it would be your duty to return a verdict in favor of the defendant." Referring to such statements, the court further said:

"You will take those facts into consideration and determine whether or not it was the intention of this language, interpreting it as an ordinarily intelligent man would, on the part of the claimants to convey the impression that they were to cure or act as a remedy for the diseases and ailments even where the language does not directly say so. If it was the intention to so frame a statement that it conveyed those impressions and those statements were false, and they are known to be false, or you can infer the intention to defraud, then it would be your duty to return a verdict in favor of the Government. If you do not find that intention, of course you will return a verdict in favor of the defendant."

See also, in answer to points, the court said, in substantial accord with *Cooper v. Schlesinger*, 111 U. S. 148, and *Lehigh Co., etc., v. Bamford*, 150 U. S. 665:

"If you find it as a fact that the statements were false, and known to be false, then, of course, your verdict would be for the Government. If you find as a fact that they were not false, or that being false there was no intent on the part of the defendant, whether actual intent or implied intent, to defraud, then your verdict would be for the claimant.

"If you believe from the evidence that any one of the therapeutic claims as to the effect of these pills upon locomotor ataxia, St. Vitus' dance, sciatica, rheumatism, impotence, spermatorrhea, or partial paralysis, was false, and was made by the claimant with a reckless and wanton disregard as to whether it was true or false, you may find a verdict for the Government."

On the whole, we may say the cause was properly tried and fairly submitted, and finding no error in the rulings, charge, points, or answers in the court below, its decree is affirmed.

CARL VROOMAN,

Acting Secretary of Agriculture.